The Scope of Medicare Reimbursement for New Medical Devices: Impact on Device Availability and the Standard of Care

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Susan B. Yeon

Evolving standards of care motivated by advances in medical technology alter the characteristics and costs of delivered health care. Faced with shifting reimbursement demands, the Health Care Financing Administration (HCFA) has promulgated regulations setting forth criteria and procedures for making coverage decisions about health care technology[1] and setting prospective payment limits for health care services including those related to new technology.[2] The effects of such regulations extend beyond the Medicare program due to the tendency of other health insurers to mirror HCFA coverage, the impact of Medicare payments on cross-subsidization and other effects of Medicare reimbursement decisions on the demand for and supply of health care.[3] The principle statutory authority for rules limiting coverage of health care technology is Section 1862(a)(1) of the Social Security Amendments of 1965 (codified in 42 U.S.C. § 1395y(a)(1)) which provides that no Medicare payment shall be made for items or services, including medical devices, which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. In 1989 HCFA proposed a rule

[1] Medicare Program: Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Teclmolgy. 54 FR 4302.4307. January 30, 1989 and 42 CER s405.380, *s405.381,* s405.382, and s 405.383 (1989).

[2] *See* Medicare: Technology Assessment and Medical Coverage Decisions, GAO Reports, July 21. 1994 and 42 U.S.C. x 1395ww(d).

[3] *See* D.A. Kessler etal., 'The Federal Regulation of Medical Devices,317 N. EnQl. J. Med. 357,3634 (l98˜).

describing criteria and procedures for health care technology Medicare coverage decisions (technology t˜J ˜ -l coverage rule).[4] The rule defines a reasonable and necessary service as one which is safe and effective, cost-effective, appropriate, and not experimental or investigational.[5] A provision of the rule categorizes a medical device that has not been approved by the FDA as experimental or investigational and hence not reimbursible under the reasonable and necessary standard.[6] In this paper I will (1) consider the legal force and implications of the provision excluding Medicare coverage of all unapproved medical devices, (2) discuss HCFA's recent efforts to investigate billing for investigational cardiac devices, (3) consider the impact of reimbursement for investigational device on device availability and (4) consider ways to reconcile prudent control of health care expenditures with expeditious promotion of high standards of health care.

1.Legal Force of The Provision Denying Coverage for Unapproved Devices

While the Social Security Amendments commit considerable discretion to the Commissioner in implementing Medicare policy,[7] HCFA's rules must conform to statutory language and intent.[8] While the statute forbids payment for any expenses incurred for items and services which are not reasonable and necessary[9] ,the terms reasonable and necessary are not defined by statute

[4]54 FR 4302,4307, January 30, 1989 and 42 CFR s405380, s405 381, s405.382, and s405.383 (1989).

[5]42 CFR s 405.380(a)(2).

[6]42 CFR s 405380(b)(2)(iii).

[7]42 U.S.C. s 1395hh(a) and s 1395y.

[8]*v. Jefferson County Bd. of Ed.,* 372 F.2d 836, decree corrected 380 F.2d 385, certiorari denied 88 S.Ct. 77,389 U.S. 840, 19 L.Ed.2d 103 (1967) (agency construction must corifomi to the law and be reasonable).

[9]41 U.S.C. s 1395y(a˜1)(A).

or explained in the legislative history.[10] As HCFA has noted, the Medicare law was designed generally to cover services ordinarily furnished by hospitals, skilled nursing facilities, and physicians.[11]

a.Process considerations

The provision denying coverage for unapproved devices (device provision) deems all such devices to be not reasonable and necessary. [12]If the device provision is categorized as a substantive rule, as case law suggests it should be, the rule lacks the force of law because it has not yet completed the required rulemaking process (discussed below). If classified as an interpretive rule, the device provision lacks the force of law since interpretive rules are merely advisory ~[13] Language in Medicare coverage manuals excluding coverage for unapproved devices is of similar, advisory, weight.[14]

Although the technology device rule contains substantive and interpretive elements, the device provision within this rule is more appropriately classified as substantive since it does more than simply clarify a statuory term or continue agency policy. [15]The provision demands per se exclusion of coverage for all unapproved medical devices even if reasonable and necessary for

[10]Senate Report No. 404 for the 1965 Social Security Aniendmerns merely states that rental of a special hospital bed for home use, massages, and heat lamp treatments would be covered only if reasonable and necessary for treatment.

[11]54FR430243()4

[12]Medicare coverage of investigational intraocular lenses was an exception to the general rule that denies Medicare payment for medical devices that have not received FDA approval. 56 FR 19874(1991). The Department of HITS made this coverage available in response to a Congressional directive **to** make the intraocular lenses reasonably available.

[13]j ~ *Casa Del Convaleciente v. Sullivan,* C.A. I (Puerto Rico) 1992,964 F.2d 1175.

[14]See Medicare Intermediary Manual and Medicare Carriers Manual, U.S. Dept. of HHS. and SeeSt. *Alarv's Hospital of Troy v. Blue Cross & Blue Shield Ass'n,* 788 F.2d 888,890 (2d Cir. 1986) and *Goodman v. Sullivan* 712 F. Supp. 334,338,891 F.2d 449(1989).

[15]*National Family Planning and Reproductive Health Ass n. Inc. v. Sullivan,* C.A.D.C.1992, 979 F.2d. 227.

patient care; this represents a substantive limitation on Medicare coverage.[16] Usually Medicare coverage decisions which affect particular therapies are considered interpretive,[17] while broad coverage decisions which limit administrative flexibility in carrying out law are considered substantive.[18]

In general, substantive rules have the force of law only if promulgated in compliance with the notice and comment rulemaking requirements of the Administrative Procedure Act and Social Security Amendments[19] The technology coverage rule has not yet completed this rulemaking process. The rule was published in the January 30, 1989 Federal Register. The comment period ended on March 31, 1989. The final rule has not yet been published, such issuance said to be pending resolution of complex policy issues.[20] Thus, the regulation does not yet have the force of law although it is entitled to substantial deference.[21]

This last conclusion presumes that the provision denying coverage for unapproved medical devices does not represent a national coverage determination (or decision) respecting a particular type or class of items. Such determinations are exempted from notice and comment requirements.[22] The

[16] 5ec *Linoz v. Heckler,* 800 F.2d 871 (1986) holding that a provision of carrier's manual carving out a per Se exception to a rule that ambulance service **to** the nearest institution with appropraite facilities was covered under medicare part B is a a substantive rule.

[17] See *Friedrich v. Secretary of Health and Human Services,* C.A.6(Ohio) 1990,894 F.2d 829, certiorari denied 111 S.Ct. 59,498 U.S. 817,112 L.Ed.2d.34 (determination by the Secretary of Health and Human Services that chelation therapy for atherosclerosis was not covered for Medicare reimbursement was interpretive rule) and *Goodman v. Sullivan,* 712 F. Supp. 334 (1989) (provision denying Medicare B coverage for NtlXls in 1985 is interpretive rule).

[18] *Flagstaff Medical Center. Inc. v. Sullivan,* C.A.9(Arix.) 1992,962 F.2d 879.

[19] Pub.L. 89-554,5 U.S.C. 553 (1966) and 42 USC § 1395hh(b).

[20] 59 FR 57600, 57602, November 14, 1994.

[21] *Good,,i˜,j v. Sullivan,* 712 F. Supp. 334,338 (1989) and *Allen v. Bergland,* 661 F.2d 1001 (1981).

[22] 42 USC x 1395ff(b)(3)(B) states that any national coverage determination under 42 USC x 1395y(a)(1) respecting whether or not a particular type or class of items or services is

exclusion of coverage for unapproved medical devices is a criterion in the national coverage determination process rather than a product of it.[23] The process for making national coverage decisions elaborated by the technology coverage rule involves identification of coverage issues for national decisions, selection of coverage issues by the Bureau of Eligibility, Reimbursement and Coverage within HCFA, and HCFA analysis which includes background papers, review by the HCFA Physicians Panel, and Public Health Service (PHS) assessment. The Office of Health Technology Assessment (OHTA) collects and evaluates information from many sources including medical literature, Federal agencies, clinical medical specialty groups, and manufacturers associations for the PHS. The OHTA report is later made available to the public. After considering the PHS coverage recommendation, HCFA decides whether or not a service should be covered using numerous criteria which consider safety and effectiveness, investigational status, and appropriateness. HCFA publishes national coverage decisions in the Medicare Coverage Issues Manual, other HCFA manuals or in the Federal Register subject to reevaluation and reconsideration.

The medical device provision is not the product of a particularized determination of coverage for particular types of services reached through the complex process described. Although, broadly speaking, it addresses a class of services-services involving investigational devices-this grouping of services in much less particular in scope than the determinations listed in the Medicare Coverage Issues Manual as national coverage decisions (coverage issues include

covered. .. shall not be held unlawful or set aside on the ground that a requirement of *5* USC § 553 or 42 USC § 1395hh(b) relating to publication or public comment was not satisfied.

[23]See 42 CFR 405.380(1989).

colonic irrigation, manipulation, and ultrasonic surgery) [24]those recognized by courts as representing national coverage decisions (covering liver transplants or chelation therapy).[25]

Should HCFA complete the rulemaking process by publishing the technology regulation in final rule form, the provision denying coverage for unapproved devices would be subject to invalidation only if found to be arbitrary or capricious or otherwise inconsistent with statutory authority. Although the arbitrary and capricious standard is narrow, it may call for invalidation of regulations if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view of the product of agency expertise.[26] The following discussion will explore aspects of the problem of reimbursement of investigational devices that Medicare coverage policy concerning unapproved devices should address.

b.The Merits of Considering all Unapproved Devices Not Reasonable and Necessary

i.Rationales for the exclusion of coverage for una˜proved devices

A number of rationales support denial of coverage for all medical devices which have not received FDA approval. First, from the standpoint of administrative economy, it makes sense for HCFA to make use of FDA ex-

[24]Medicare Program; National Coverage Decisions, 54 FR 34555,34556, August 21, 1989.

[25]˜See *Presbyterian University Hospital of Pitt.sburgh v. lacovetto and Bowen* 1989 WL 248274 (W.D.Pa) (denying benefits for liver transplants is a national coverage determination) and *Friedrich v. Secretary of Health and Human Services* 894 F.2d 829(6th Cir. 1990) (denying payment for chelation therapy is a national coverage determination).

[26]*Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co..* 463 U.S. 29, 103 S.Ct. 2856,2866,77 L.Ed. 2d 443 (1983) cited in *St. James Hosp. v. Heckler,* 760 F.2d 1460

pertise, resources and judgments in evaluating the reasonableness and necessity of devices [27] While HCFA may superimpose its own appraisals of cost-effectiveness, clinical use, efficacy and safety in determining suitability for coverage,[28] it should not wastefully duplicate the efforts of the FDA. Both the FDA and HCFA lack sufficient resources to keep up with demands for technology assessments.[29] With only five professional staff the Office of Health Technology Assessment studies HCFA's requests for technology assessments of national concern to Medicare, ORTA has evaluated fewer than 10 technologies per year.[30] As a result, HCFA relies on its 79 Part A and Part B contractors to make most Medicare coverage decisions.[31] Reliance upon FDA approval status in making coverage decisions may help avoid additional uncertainty and duplication in a technology assessment system which is already overburdened.

Second, HCFA may favor a broad rule to protect Medicare patients from inefficacious or unsafe devices and to assure that Medicare dollars will not be fraudulently diverted to pay for research on unproven therapies. Patients rely on HCFA to protect the quality of care which they receive especially since they are often less than fully informed about the potential benefits and risk of recommended therapies. Physicians have ethical and legal obligations to provide appropriate care but such obligations imperfectly safeguard the

[27] D.A. Kessleretal., 'The Federal Regulation of Medical Devices, 317 N. Engi. J. Med. 357,363(1987).

[28] See 54 FR 4302.4307.

[29] Senator Kennedy, Statements of Introduced Bills and Joint Resolutions, 140 Cong Rec 5 8821 (1994) (noting the mismatch between the eniand for agency review and declining FDA resources). and Medicare: Technology Assessment and Medical Coverage Decision, GAO Reports, July 21,1994.

[30] kL

[31] Id.

quality of care received by patients.[32] HCFA acts to protect the standard of care received by Medicare patients both through the Utilization and Quality Control Peer Review Organizations as well as through general oversight and administration of the Medicare program.[33] If payment for unproven devices were readily reimbursible, unscrupulous or misinformed physicians might more readily recommend these devices to their patients. Patients might understandably interpret HCFA's reimbursement for treatment with such devices as signifying endorsement of that treatment. r

Third, restriction of reimbursement for investigational devices reinforces incentives for device manufacturers to comply with and complete the FDA approval process. Since these manufacturers must obtain FDA approval in order to market their devices and recoup the frequently enormous investments they have made in research and development, they are motivated to comply with FDA requirements.[34] These FDA requirements attempt to insure acceptable levels of safety and effectiveness before a device is placed on the market. Although the FDA device approval system has been subject to criticism,[35] it does promote a knowledge-based approach to use of medical devices because it encourages manufacturers to sponsor scientifically and ethically sound studies of their devices. The potential for abuse of the the investigational device

[32] 5ee Harvard Medical Practice Study, Patients, Doctors, and Lawyers: Medical INjury, Malpractice Litigation, and Patinet Compensation in New Yprk, Exec. Sunim. (1990).

[33] Practising Law Institute, Public Health Care Reimbursement Programs, Health Care Law p.206 (1993). PROs determine whether health care services provided to Medicare beneficiaries were of a quality which meets professionally recognized standards of health care, 42 U.S.C. x 1320c-5.

[34] **2i** USC s 351(f)(2)(B) (1982).

[35] Dissenting views, Medical Device User Fee Act of 1994, 103 H.Rpt 751, (discussing a highly cntical reprot on FDA device management entitled Less Than the Sum of Its Parta)

process is demonstrated by the case of C.R. Bard Inc., a manufacturer that agreed to pay $ 61 million in civil and criminal fines after pleading guilty to 391 criminal charges related to the sale of untested cardiac catheters, illegal clinical experimentation and concealing serious device flaws.[36]

Fourth, denial of reimbursement for investigational devices may help slow the rise in Medicare reimbursement costs. New technology is a frequently cited cause for increases in health care costs. Medicare has attempted to account for the costs of new technology by revising DRG weights, rearranging DRG assignments, and occasionally creating new DRGs.[37] HCFA is required by law to revise the DRG system each year. Since dollars available to spend on Medicare reimbursement is limited, excluding payment for investigational devices may provide a mechanism for rationing those dollars.

Finally, a broad rule excluding all unapproved devices is easier and less cosdy to administer than rules providing more particularized guidance for judging the reasonableness and necessity of medical care. Ironically, administrative costs incurred limiting coverage for the purpose of cost-control can result in overall increases in health expenditures.[38] Easy to apply coverage decisions save administrative costs leaving more health care dollars available to pay for health care.

[36]Vera Titunik, Northeast, *U.S. v. C.R.Bard,* The American Lawyer, December 1993, p.86 and Robert Pear, Medicare Inquiry Subpoenas lOOHospitals. N.Y. Times, June 18,1994, at 11.

[37]Medicare: Technology Assessment and Medical Coverage Decisions, GAO Report, July 21,1994.

[38]5ee S. Woolbandler and D. U. Hiinmelstein, 'The Deteriorating Administrative Efficiency of the U.S. Health Care System, 324 N.EIIRI. J. Med. 1253(1991) and D.A. Redelmeier and yR. Fuchs, Hospital Expenditures in the United States and Canada, 328 N.Ennl. J. Med. 772(1993).

ii.Criticiue of the exclusion of covera2e for unanproved devices

Although the rationales for denial of coverage for investigational devices have some force, the consequences of such denial may not be as favorable as those rationales suggest.

First, an absolute requirement of FDA approval may not properly provide for the reasonable clinical needs of many patients. While the requirement for FDA approval appropriately excludes coverage for devices which FDA has rejected as well as for untested devices, it also excludes payment for unapproved devices which are reasonable and necessary for health care. The FDA itself has accepted departures from the approval process thus acknowledging that unapproved medical devices may be required for emergency use[39] and that unapproved uses of approved drugs may be medically appropriate.[40] Courts interpreting insurance contracts which restrict coverage to

11 medically necessary treatments have held that a treatment need not be FDA approved in order to be medically necessary.[41] The chief difficulty with reliance on FDA approval as a standard for reimbursement is that such standard tends to lag behind medical progress because of delays in agency review. Limitations in FDA resources produce substantial backlogs, the number

[39]Guidance for the Emergency Use of Unapproved Medical Devices; Availability

[40]37 FR 16,5(13 (1972). The legitimacy of certain off-label uses has also been recognized by courts and state legislatures. In *Weaver v. Reagen* , 886 F.2d 194(8th Cir. 1989). the court found that off-label use of AZT may be medically necessary and thus warrant **Medicare coverage. New York and** Michigan statutes forbid insurers from excluding coverage of off-label uses of certain cancer drugs, N.Y. Ins. Law § 3216(h)(12) (McKinney Supp. 1991) and Mich. Comp. Laws Ann. §§ 333.21054b (West 1991).

[41]5ee *Mc Laughlin v. Connecticut General Dfe Ins. Co.* (1983, ND Cal) *565* F. Supp. 434 (Despite lack of FDA approval for immunonugmentive therapy such treatment was medically necessary with the meaining **of insurance policy) and** *Schumake v. Travelers Ins. Co.* (1985)147 Mich **App** 600,383 NW2d 259 (Laetrile treatments were medically necessary within meaning of insurance policy because patients physician recommended them before they were discredited.)

of overdue 510(k) submissions increasing from 330 in 1992 to 1,895 in 1993. 510(k) review times rose from 98 days in 1990 to 213 in 1994.[42] Review times for premarket approval applications rose from 415 days in 1990 to 840 in 1994.[43] When the technology coverage rule was first published in 1989 the requirement for FDA approval might have been expected to cause minimal delay in the availability of useful, new medical devices. The increased FDA backlog since then has increased the impact of the FDA approval requirement since it is now more likely that reasonable and necessary devices will remain unapproved for significant periods of time.

Second, although denying payment for service considered experimental or investigational is a standard method of avoiding diversion of funds for clinical care to fund research, such terms may obscure the complexity of distinguishing research from clinical purposes and distinguishing unproven from proven therapy. Ethical clinical research depends on the presumption that study of a device to further define its clinical benefit can be made consistent with the appropriate treatment of patients participating in

12 the clinical trial. Although investigational is commonly understood as being synonymous with experimental or unproven, investigational is a also a term of art in the FDA device approval process. Medical devices which are awaiting FDA approval for marketing receive investigational device exemptions for clinical testing and limited clinical use. A device may be investigational in the sense of not having received marketing approval although its effectiveness

[42] 140 **Cong Rec 5 8821, July 12, 1994.**

[43] 103 H.Rpt. 751, Medical Device User Fee Act of 1994, Dissenting **views, Sept. 26, 1994.**

and safety has been scientifically proven. While the FDAs role as protector of the safety of the medical devices requires it to forestall approval of such devices until it has the time to evaluate their risks, sick patients also face the risks of their own illnesses which require treatment in a timely fashion. A delay in device approval in the name of safety may actually produce a net loss in lives and increase in morbidity.[44]

The technology coverage rule itself contains provisions which attempt to accommodate urgent needs for medical care which cannot wait for slow, albeit sound, administrative approval processes. First, the rule provides for coverage of certain investigational cancer drugs for terminally ill cancer patients.[45] Second, the regulations note that less stringent standards for safety and effectiveness will be applied to breakthrough medical or surgical procedures.[46] Third, the regulations contemplate the coverage of off-label use of drugs and devices should such use be medically appropriate.[47] However, the regulations do not provide coverage for critically ill patients who may require treatment with investigational devices as urgently as terminally ill cancer patients require investigational drug treatment. The provision permitting less stringent proof of safety and effectiveness for breakthrough medical or surgical procedures conflicts with denial of payment for investigational devices since many of these breakthrough medical or surgical procedures require investigational devices for

[44]5ee M. Kinsley, 'The FDA: Too Cautious, Not Too Bold, The Washin2ton Post, August 10, 1989, p. **A25 (citing coniplaints that the slow FDA approval process may be detrimental to the public's health but also cautioning that abandonment of regulation would also be unwise).**

[45]**42 CFR Part 405.380 (b)(2)(ii).**

[46]See 42 CFR Part 405380 (b)(1)(v)

[47]54 FR 4302,4306.

their implementation.

Third, denial of Medicare reimbursement for all investigational devices is not a prerequisite for assuring that device manufacturers comply with the FDA approval process. If reimbursement for investigational devices were subject to limitations such as facility or patient selection criteria as well as subsequent revision, manufacturers would remain motivated to obtain FDA approval. Current FDA regulation prohibits investigators from charging subjects a price larger than that necessary to recover costs of manufacture, research, development and handling. The FDA has recently published an Advance Notice of Proposed Rule-Making (ANPRM) indicating that it is considering revising the regulation to further limit charging for investigational devices. While allowing manufacturers to charge for investigational devices may encourage the development of medical devices such payments should not be permitted to allow manufacturers to earn profits and thus escape the requirement of the FDA.

If the payment manufacturers receive for investigational devices is limited, the chief effct of permitting coverage for investigational devices may be to reimburse hospitals for providing services related to the medical device use.

Fourth, although denial of payment for all investigational devices may decrease the cost of Medicare reimbursement such cost-cutting is justifiable only if it is consistent with appropriate medical care. Potential gains in cost-containment from such denial must be balanced against potential health benefits lost. Such balancing is not possible when an across-the-board rule is in effect. An across-the-board exclusion of unapproved devices is inconsistent with the

detailed criteria and procedures for HCFA decisions for health care technology set up in the technology coverage rule. Furthermore, denial of reimbursement for medically necessary investigational devices will not necessarily save Medicare costs. If use of an investigational device offers care that is safer or more effective or more appropriate than available alternatives, Medicare expenditures may actually increase if coverage for the investigational device is not made available.

Finally, low administrative cost does not justify adherence to a rule which produces unfair results. Although no administrative process can perfectly identify reasonable and necessary services, denying coverage for all investigational devices may approach the decision by too rough a cut. If some investigational devices are necessary for appropriate medical care, the denial of reimbursement for such devices might trigger a variety of consequences contrary to law and public policy. If many provides and patients dispute denial of coverage for investigational devices the initial administrative cost savings may be lost.

Even if a device is inexpensive or free, Medicare denial of payment for all services related to an excluded service may result in substantial uncovered costs.[48] For example if a patient is hospitalized and has a procedure performed involving an unapproved device, Medicare policy suggests that payment may be denied not only for the procedure but also for the entire hospitalization if the admission was related to preparation for the uncovered procedure.

Consider the following potential consequences of denial of coverage

[48]**Services related to or required as a result of prior noncovered services CCH ∂4030.78(1994), Medicare** Carriers Manual § 2300.1; Medicare Intermediary Manual x**3101.14.**

for necessary investigational devices:

1.Hospitals and physicians continue to provide the investigational device to some or all patients for whom the device is appropriate. a.Patients with sufficient funds or other insurance coverage to pay for the investigational device pay health care providers for the device and related services. However, patients told that Medicare has determined that such care is not reasonable and necessary may refuse treatment on the basis of that judgment even though the device is actually reasonable and necessary for their care.[49] b.i. Patients lacking funds or insurance to pay for the investigational device receive the device and related services free of charge. Costs of the device and related services may be shifted to other insurers and patients. Hospitals that continue to provide the device may suffer considerable Ions and may be put at a competitive disadvantage because they have fewer funds available to provide services or amenities compared to hospitals who do not suffer the expense of providing such charity. cr ii.Patients who are unable to pay for the device are selectively denied the device. They may then receive care that is less appropriate or beneficial than treatment involving the investigational device. However, Medicare regulations provide for termination of providers who discriminatorily deny care to Medicare patients.[50]

[49]Medicare policy attempts to avoid reliance upon its denial of payment decisions as evidence that a physician's choice is inappropriate or that a patinet does not need treatment by providing a full explanation of the true import of denial in denial notices. However, patients informed by their physicians that a treatment is not covered by Medicare may not receive such notices should they refuse treatment and thus not produce a payment claim.

[50]42 C.F.R.s 489.53(aX2) provides that HCFA may terminate the agreement with any provider if HCFA finds that a provider places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restzictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care.

2. Physicians and hospitals are dissuaded from offering medically appropriate investigational devices to all patients. Although Medicare's technology rule directly applies only to Medicare patients, health care providers may deny the technology to all patients for two reasons. First, the scope of coverage by other insurers often mirrors that of Medicare so patients who have insurance other than Medicare may also lack coverage for the devices.[51] Second, denial of access to the unapproved technology to all patients avoids charges of discrimination. [52]

Tort law demands that health care providers provide appropriate care. Although use of an investigational device is not generally thought of as standard for malpractice purpose, courts have noted that physicians with special knowledge or expertise are required to employ such faculties in treating their patients.[53] In addition, a rule awaiting final publication authorizes Peer Review Organization to deny Medicare payment to a for substandard quality services.[54] Denial of medically necessary investigational devices to patients also violates ethical obligations of physicians and hospitals to provide appropriate care but such denial may be induced, even mandated, by denial of Medicare reimbursement. Thus, across the board denial of reimbursement for investiga-

[51]For example, a regulation governing benefits under the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) excludes coverage for devices that have not been approved by the FDA. See also, Bechtold v. Physicians Health Plan of Northern Indiana, Incorporated, 19 F.3d 322,325 (1994) in which an employee welfare benefit plan denied coverage for any procedure, device, or drug which any government agency, including the FDA, the Office of Technology Assessment, and the HCFA Medicare Coverage Issues **Manual considers to be experimental or investigational or not reasonable and necessary.**

[52]5ee 42 C.F.R s 489.53(aX2), n.50.

[53]5ee *Burton v. Brooklyn Doctors Hospital,* **88 A.D.2d 217, (1982). The court endorsed the following jury charge: If a physician fails to employ his expertise or best judgment, and that omission causes injury, he should not automatically be freed from liability because in fact he adhered to acceptable practice.**

[54]54FR 1956, January 18, 1989.

tional medical devices may conflict with HCFAs goals of protecting the quality of care received by Medicare patients and of assuring that Federal funds are expended only for medical services that are appropriate to meet an individual's medical needs.

HCFA's Investigation of Billing for Investigational Cardiac Devices

HCFA has signaled interest in enforcing the exclusion of coverage for investigational devices. In June of 1994 June Gibbs Brown, the inspector general of the Department of Health and Human Services issued subpoenas to 132 hospitals to determine whether the hospitals had submitted false or improper claims to Medicare and Medicaid for the use of medical devices not approved by the FDA.[55] Some cardiac device manufacturers were also subpoened for information on sales of unapproved medical devices to hospitals.[56] The investigators are presumed to be looking for cases in which Medicare and Medicaid were billed for the use of investigational devices including cases in which hospitals billed Medicare for purchase of devices which they had received free of charge from manufacturers. The probe is also apparently looking for any illicit financial incentives manufacturers may have given hospitals related to their use of unapproved devices.[57] Such incentives could represent violations of the Medicare and Medicaid fraud and abuse provision which imposes criminal penalties for iligeal remuneration to induce referrals or purchases.[58]

[55]R. Pear, Medicare Inquiry Subpoenas 100 Hospitals, N.Y. Times, June 18, 1994, at 11 and S. Shepard, HCFA may request paybacks on medicare payments; Health Care Financing Administradon, MemDhis Business Journal, December **19, 1994, at. 23**

[56]Barlas, Pete, Ventritex Included in Medicare Investigation, 12 ˜ **3. August 1, 1994.**

[57]FDC Reports Inc., The Gray Sheet 1994. June 27, 1994.

[58]42 U.S.C. § 1320a-7b(b).

The apparent impetus for the investigation was a whistle-blower lawsuit filed in Seattle.[59] The subpoenas requested lists of all procedure performed from April *5,* 1984 through March 31, 1994, involving devices not approved by the FDA for marketing, including unapproved uses of approved devices. The subpoenas were later limited to the use of nonapproved devices.

The False Claims Act provides for civil penalties for any person who knowingly presents or causes to be presented...a false or fraudulent claim for payment or approval or who creates or uses a false record to get a false or fraudulent claim paid by the Government.[60] Discontinuities in hospital billing processes might result in inadvertant billing for investigational device. However since acting with deliberate ignorance or reckless disregard of the trust or falsity of information is sufficient to meet the knowing or knowingly standard, lack of actual knowledge of a false claim is not a defense to a false claim charge. On the other hand, as noted above, the provision excluding Medicare coverage for devices unapproved by the FDA has not completed the rulemaking process so its legal force as a basis for refunds and penalties is subject to dispute.

Physicians contend that some investigational cardiac devices have become elements of the standard of medical care, particularly in situations in which they save patients from more risky and expensive procedures such as surgery. Thus, these devices are reasonable and necessary to health care despite their unapproved status. An example is the implantable cardioverter defibrillator (LCD). An LCD responds to potentially lethal cardiac rhythm disturbances

[59]McCormick, Brian, IG **has 'dragnet'booking into cardiac fraud, 37 American Medical News 64, November 7.1994.**
[60]**31 U.S.C. s3729.**

by delivering electric shocks to the heart. Although the first LCD-type device was approved by the FDA in 1985, the FDA has been slow to approve improvements in the devices, slowing the availability of improved devices to patients who are at high risk for sudden death.[61] Implantation of the leads for these devices originally required open chest surgery but newer lead systems are now available which permit implantation transvenously (through veins which lead to the heart) and which are associated with significant decreases in perioperative mortality. Approval of the premarket application for the first of these devices, the Endotak, took about 17 months. Although this approval time is a typical one for the agency, the restricted availability of the device during the approval process created concerns that patients were being denied lifesaving therapy. While two of these transvenous lead systems have received FDA approval for marketing,[62] the FDA has not approved use of these lead systems in combination with ICDs which were not referred to at the time of the premarket approval.[63]

The Impact of Medicare Reimbursement For New Devices on Device Availability

Medicare coverage and reimbursement decisions affect the availability of devices which have already been developed and expectations for device development in the future.[64] These decisions affect the liklihood that patients

[61] 0ne device approval took two and one-half years after the preinarket approlcation was completed despite panel recommendation for approval. See D.M. Steinhaus, How Should FDA Regulation of Devices Change? 48 Food **and Dma L. J. 709(1993).**

[62] See D.M. Steinhause, n. 52 at 710.

[63] 1n a Decemba˜ 1, 1993 warning letter the FDA stated that Ventritex must issue Dear Doctor letters retracting a promotion it had carried out recommending use of its lCD with CPI's Endotak leads because such combination had not received FDA approval.

[64] D.A. Kessler et al., 'The Federal Regulation of Medical Devices, 317 N. EnnI. J. Med.,

will be offered treatment with a new device because they affect the degree to which manufacturers will be motivated to make the device available as well as the financial incentives of hospitals to either encourage or discourage physicians from making use of the device. In the long run, availability of insurance coverage for new devices impacts the intensity of development of new technology because the promptness and amount of such coverage influences the likelihood that a manufacturer will be able to recoup its substantial investments in research and technology.

Doubt about Medicare coverage may chill use of a device and innovation of it. Industry officials assert that the HHS probe of cardiac devices is limiting access of Medicare patients to invasive cardiology services and warn that it may encourage manufacturers to investigate or release medical devices abroad.[65] Kristen Morris, director of government affairs for the Health Industry Manufacturer's Association, contends that the threat of loss of Medicare payment for investigational devices is slowing the development of new products in the cardiac field.[66]

Even new technologies which are unambiguously covered by Medicare may be discouraged if they are undercompensated. A recent study demonstrated that Medicare's prospective payment system systematically undercompensates non-capital technology costing $1,000 or more.[67] An example is the

357,3634 (1987) and N.A. Kane and P.D. Manoukian, Prospective Payment System and New Technology, 32 ˜ Enal. J. Med. 1378(1989).

[65]5ee McCormick, Brian, IG has 'dragnet'looking into cardiac fraud. 37 American Medical News 64, November 7,1994 and Barlas, Pete, Ventritex included in Medicare **investigation. 12 ˜j 3, August 1.** 1994.

[66]McCormick a..54.

[67]Kathryn S. Taylor, 'Tech-intensive DRGs: Study finds bias toward underpayment, 68

implantable cardiac defibrillator for which the average payment from Medicare is $34,000 while the average cost is $38,000.

The history of the cochlcar implant demonstrates the effect Medicare DRG assignment can have on the adoption of new technology.[68] Although epidemiologic data suggests that large numbers of people with hearing disabilities might benefit from this device, it has been implanted in relatively small numbers of people since it was approved for marketing by the FDA in 1984. The device had been covered by Medicare since 1986 but it has been assigned to a DRG with a payment level well below its cost. This led hospitals to ration the availability of the device so that very few devices were implanted (only 69 cochlear implants in fiscal 1987). 3 of the *5* firms in the cochier implant market left it. N.M. Kane and P.D. Manoukian suggest that the reason cochlear implants were not more widely adopted is because physicians wanting to perform the procedure had to overcome the hospital's strong financial disincentives.[69]

HCFA has received complaints that the weight of the DRG 49 for cochlear implants is too low since it published the prospective payment rule in September 3, 1986.[70] 100 Medicare cochlear implant cases occured in 1991. Although the agency noted that cochlear implant incurred higher charges than the average for its DRG the agency concluded that the volume of cases did not justify a DRG modification.[71] While this conclusion may serve administrative

Hosuitals **70(1994).**

[68] N.A. Kane and PD. Manoukian, Prospective Payment System and New Technology, 32 N. En2l. J. **Med. 1378(1989). (The article also refers** to **the role of reimbursement on the availability of penile prostheses and hip implants.)**

[69] 1d at 1380.

[70] FR 46270,46273 (1993)

[71] ~ FR39755 (1992).

economy, it is an ironic one because it may cause low volume use to continue since the DRG assignment is likely depressing the volume of cochlear implant cases. There were a total of 81 cochlear implant Medicare cases in 1993.[72] In 1993, HCFA moved the lowest charge procedure in the DRO which resulted in a slight increase in the average charge for DRG 49. The effect, if any, of this change on the volume of procedures has not yet been published. The agency responded to criticism of below cost reimbursement for cochlear implants by stating that it is providing an incentive for hospitals to treat a mix of patients and to offset losses with gains.[73] Since hospitals have many sources of bad debt and must meet demands for charity to satisfy state and federal law[74] they risk financial instability depending upon the reimbursement mix of patients they treat. Although hospitals may cost shift, they ultimately face a financial bottom line vulnerable to unrelieved losses. Furthermore, for-profit health care providers may exhibit profit-maximizing behavior.[75] The agency responded to a comment that cochlear implants may not be available to Medicare beneficiaries in the future by noting that a hospital may be terminated from participation in Medicare if it places restrictions on the persons its accepts for treatment which it does not apply equally to Medicare patients as to all other persons.[76] While

[72] ~ 45330,45343 (1994).

[73] **Id.**

[74] Federal law as well as the statutes of several states (e.g. N.Y. -McKinne˜s Pub. Health Law §2805-b(2))require hospitals to provide emergency care. See the Emergency Medical Treatment and Active Labor Act 42U.S.C.§ 1395dd.

[75] G de Umiovoy et al., 'The relationship of provider organizational status and erythropoietin dosing us end stage renal disease patients, 32 Med Care (United States) 130 (1994) (With fixed Medicare payment per dose of erythropoietin (EPO), for-profit, free-standing providers prescribed EPO more often and in smaller doses than nonprofit or government providers, such behavior being consistent with profitmaximization.)

[76] 1d citing 42 CER 489.53(a)(2).

the regulation barring discriminating against Medicare patients may prevent hospitals from selectively excluding them (at least overtly) it does not protect against the concerns that all patients may have restricted access to cochlear devices and that the quality of these devices is not what it might have been had the demand for the devices been allowed to more closely matched the need for them. Evidence indicates that low volume of sales has dissuaded a manufacturer from improving the device.[77]

Potential Solutions

a.Coveraae for The ADDroDriate Use of Investigational Devices

Although a rule excluding Medicare coverage for all devices unapproved by the FDA may be easy to administer, it is likely to discourage and penalize provision of some types of reasonable and necessary care to Medicare patients. A more flexible rule allowing reimbursement for appropriate use of investigational devices could avoid this problem. While a default rule of denial of reimbursement for unapproved devices could apply, physicians and patients would be allowed to show that reasonable and necessary care requires use of an investigational device. In order to insure that investigational devices are used appropriately, Medicare reimbursement could be made contingent upon use under an Investigational Device Exemption and satisfaction of specific facility and patient selection criteria, as may be required for breakthrough procedures. [78]

A more rapid FDA approval process would help decrease the num-

[77]**See N.M. Ku˜e and P. D. Manukian a. 58, at 1380 noting that the 3M Company stopped actively marketing the single-channel model and halted research on the mutichannel device because of the low volume of sales.**

[78]See 42 CFR Part 405.380 (b)(lXv), provision on breakthough procedures.

ber of medically necessary, unapproved devices. An increase in the medical device user fee (analogous to the prescription drug fee) paid by device manufacturers to the FDA could be used to pay for increased FDA staff and resources to help speed the FDA clearance process[79] and thus lessen the delay between proof of clinical effectiveness and FDA approval for

24 marketing. Device manufacturers have signaled their willingness to pay such an increased fee.[80] If the fee leads to a speedier approval process, device manufacturers would save costs incurred by delays in the approval process. Patients and physicians would benefit from more rapid availability of beneficial devices and perhaps reduced device costs. Insurers, including HCFA, would benefit from being able to rely on the FDA for timely advice concerning new developments.

b.Reimbursement for New Devices

The DRG system as currently applied tends to undercompensate new technologies because new devices are often placed in DRGs with average costs below those of the new device.[81] In each DRG, HCFA attempts to classify clinically similar patients who use approximately the same amount of hospital resources. HCFA also attempts to maintain enough cases in each DRG to allow for stability within the DRG over time.[82] While this classification scheme is

[79]Such a fee was proposed in bills introduced to Congress in 1994 under the sponsorship of Senator Edward M. Kennedy and Representative Henry A. Waxman. S.22'76, 140 Cong Rec 58821 and fIR 4864, 140 Cong RecE 1442.

[80]**The Health Industry Manufacturers Association, representing manufacturers of over 90 percent of U.S. health technology endorsed the 1994 140 Cong. Rec. 8821.**

[81]Kathryn S. Taylor. 'Tech-intensive DRGs: Study finds bias toward underpayment, 68 Hospitals 70(1994).

[82]59 FR 45330.45343.

well-suited to devices whose clinical use and costs are expected to be relatively stable over time, it may tend to chill usage and development of new devices. If a new technology provides benefits that are substantially greater than those provided by older technology, paying a higher price for the new device than for the lesser alternatives may be justified even in a cost-conscious health care system. New devices may be expected to show more improvement in cost and refinement in the years immediately following their release than devices which have been available for a long time because substantial gains in information about their clinical and technical properties and their manufacture are more likely. A liberalization of DRO categorization in the early years of product release would improve access to new devices and incentives to develop them.[83] A relatively high cost for a device may be justified early on if the cost can be expected to later decline through the effects of efficiency and competition. After a -few years the device could be assigned to a more stringent category of reimbursement reflective of a maturing industry. The prices of even such complex technologies as bone marrow transplants have declined due to advances in technology and efficiency (although critics suspect some of the price cuts come at the expense of quality or are achieved by cross-subsidies).[84]

Conclusion

Although Medicare reimbursement for health care services is not aimed at funding or stimulating research, Medicare law is designed to protect

[83]N.A. Kane and P.D. Manoukian, Prospective Payment System and New Technology, 32 ˜L˜ggjJ.. Med**. 1378, 1382 (1989).**

[84]**George Anders, On Sale Now at Your HMO: Organ Transplants, Wail Street Journal, Jan. 17.1995 at Bi.**

the quality of health care available to Medicare beneficiaries. The quality of care depends upon access to new technology today and in the future. Reimbursement mechanisms which undercompensate new technology may slow increases in health costs by diminishing the influence of technological developments on the standard of care, eliminating some waste but also some innovation. Medicare policy should not draw so tight a circle around existing practice that the benefits of new developments are left out.